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10/027,625	12/21/2001	Sabine Stumvoll	25401-5	1495

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/027,625	STUMVOLL ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 08/04/2008 is acknowledged.

2. Claims 30-36 are pending and currently under consideration as they read on a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, comprising selecting an individual known to be weed pollen, wherein it is not known if the individual is *Parietaria* allergic; selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity; contacting serum from an the selected individual with the pure allergen component, wherein the pure allergen component is pure Par j 1 or Par j 2 allergen component; determining the presence of IgE binding to said pure Par j 1 or Par j 2 component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

3. In view of the response filed on 08/04/2008, the following rejections are maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 30-32 and 34-35 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP 0707065 A2 (IDS filed on 07/01/2002) for the same reasons as set forth in the Office Action mailed on 04/03/2008.

EP 0707065 teaches a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic (grass allergic) as *Parietaria* allergic, comprising selecting an individual known to be weed pollen allergic (grass allergic), wherein it is not known if the individual is *Parietaria* allergic; selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity; contacting serum from an the selected individual with the pure allergen component, wherein the pure allergen component is pure Par j 1 allergen component; determining the presence of IgE binding to said pure Par j 1 component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component; wherein the pure allergen component is recombinant Par j 1; and further comprising selecting an allergy treatment involving extract, proteins or peptides derived from a *Parietaria* species for an individual identified as *Parietaria* allergic. (In particular, page 4, lines 41-47, page 5, lines 31-32, page 7, lines 5-31, page 8, lines 49-59, Figure 8, abstract).

It is noted that the recitation of "an individual known to be weed pollen allergic" is anticipated both by grass pollen allergic individuals shown in Example 8 and by the fact that the diagnostic method of EP 0707065 is directed toward diagnostic procedures for all individuals. Grass pollen allergic individuals are a subset of all individuals which are encompassed by the

teachings of the reference. A diagnostic procedure which identifies *Parietaria* allergic individuals from all individuals will inherently identify *Parietaria* allergic individuals from weed pollen allergic individuals.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 08/04/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "Thus, the present methods are for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic but it is not known if the individual is *Parietaria* allergic. Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while the recited pure allergen component Par j 1 or Par j 2 does not bind to IgE from such individuals. However, Par j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen, as does Par j 1. Thus, Applicants have developed the present methods for specific identification of *Parietaria* allergic individuals from those known to be weed pollen allergic using a pure allergen component known to have limited or no cross-reactivity.
>
> Ep '065 was cited in Applicants' Information Disclosure Statement and is discussed at page 2 of the present application. EP '065 describes recombinant *Parietaria* proteins and derived peptides for use in therapy and diagnosis of *Parietaria* pollen-induced allergy. However, EP '065 does not disclose or teach the use of a pure allergen component and does not teach the use of any of the proteins or peptides as reagents to distinguish between genuine *Parietaria* pollen sensitization and cross-reaction-mediated seropositivity to *Parietaria* pollen extract. In fact, in the "Immunoassay" discussion at page 7, lines 5-31, EP '065 discloses that a mixture of peptides may be used either as an immunogen in a composition or as a diagnostic agent, thereby demonstrating the EP '065 does not contemplate the use of a pure *Parietaria* allergen component, particularly a pure *Parietaria* allergen component known to have limited or no cross-reactivity, as compared with mixtures of *Parietaria* allergen components having cross- reactivity.
>
> Further, while the Examiner relies on Example 8 of EP '065, Example 8 does not disclose identification of an individual known to be weed pollen allergic as *Parietaria* allergic that is required by claim 30 and does not indicate that a pure *Parietaria* allergen component known to have limited or no cross-reactivity is employed so that the presence of IgE identifies an individual as *Parietaria* allergic, rather than exhibiting cross-reactivity to one or more *Parietaria* allergens. To the contrary, EP '065 discloses that western blot analysis "of *Parietaria* protein extracts" (page 11, lines 55-56, emphasis added) was conducted. Thus, Example 8 employed extracts, not a pure allergen component. Additionally, EP '065 discloses that using "pools **of** sera" (page 11, line 56, emphasis added) from Italy and Canada showed that a

14 kDa component was recognized by both pools of sera. One of ordinary skill will appreciate that using pooled sera does not provide any diagnostic value relative to an individual.

As disclosed in the present application, for example at page 4, *Parietaria* is a Mediterranean weed. In this regard, the Examiner's attention is directed to the attached copy of a map from the website of the Global Biodiversity Information Facility (www.gbif.org) showing the worldwide known occurrences of *P. judaica,* see http://data.gbif.org/species/13731576. According to this resource, *P. judaica* is not reported as occurring in Canada, thus Canadian patients can be anticipated to have a very low risk of being primarily sensitized to *P. judaica pollen. Yet the Canadian patients in EP ' 065 have IgE that binds to extract of P. judaica* pollen, which binding may well be due to components of the extract that are cross-reactive. As demonstrated in the present specification, patients from the U.S. (having very few occurrences of *P. judaica)* did not have any IgE against the pure allergen component Par j 2, despite showing binding to *P. judaica* extract. That is, the present specification, at page 4, lines 4-6, discloses that sera from patients from Scandinavia, the U.S. and Austria contained IgE that binds to components in *Parietaria* extract (i.e. not pure components). However, only a few Austrian and no Scandinavian or American patients' sera had IgE that bound to Par j 2 (i.e. to the pure component). On the other hand, the Mediterranean patients, who are primarily sensitized to *Parietaria,* contained IgE that bound to Par j 2.

Anticipation under 35 U.S.C. § 102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson,* 169 F.3d 743,745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill; inherency may not be established by probabilities or possibilities and the mere fact that a certain thing may result from a given set of circumstances is not sufficient, *In re Robertson,* 49 U.S.P.Q. 2d 1949, 1950-51 (Fed. Cir. 1999). Similarly, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic, *In re Rijckaert,* 28 U.S.P.Q. 2d 1955, 1957 (Fed. Cir. 1993).

EP '065 fails to teach the use of a pure allergen component for serologically identifying an individual, particularly for serologically identifying an individual as *Parietaria* allergic, and EP '065 fails to teach or suggest selecting a pure allergen component known to have limited or no cross-reactivity. Accordingly, EP '065 does not disclose each and every element as set forth in the claims and therefore does not anticipate the presently claimed methods. While the Examiner has asserted that the steps of the present methods are inherent in the teachings of EP '065, specifically that identifying *Parietaria* allergic individuals from all individuals will inherently identify *Parietaria* allergic individuals from weed pollen individuals, the Examiner has not demonstrated any extrinsic evidence which makes clear that the missing elements are necessarily present in the EP '065 teachings, and that the claimed methods would be so recognized by persons of ordinary skill. To the contrary, the teachings of EP '065 relating to the use of a mixture of peptides for diagnostic use (page 7, lined 16-17) and *Parietaria* extract with pooled sera (page 11, lines 55-57) contradict the Examiner' s assertions regarding inherency as no pure allergen component is employed and no individual is diagnosed using the pooled sera. Thus, EP '065 does not inherently describe the claim elements. Accordingly, EP '065 does not anticipate the present claims under 35 U.S.C. § 102, whereby the rejection has been overcome. Reconsideration is respectfully requested."

It remains the Examiner's position that EP 0707065 anticipates the claimed invention because it specifically teaches the use of purified Par j 1 to diagnose *Parietaria* pollen allergy. Throughout the reference, Par j 1 was purified and contacted with serum and the reference

teaches its use to diagnose *Parietaria* pollen allergy. Specifically, in Figures 1 and 9 (Examples 1 and 8) *Parietaria* pollen extracts were separated/purified by SDS PAGE and Western blots were performed using serum from *Parietaria* pollen allergic individuals. Knowledge of non-cross-reactivity of Par j 1 is not necessary to anticipate the claimed invention. The reference teaches the use of the same compound to diagnose the same allergy in the same population, therefore the claims are anticipated.

Applicant's argument that the reference does not disclose or teach the use of a pure allergen component, particularly a pure *Parietaria* allergen component known to have limited or no cross-reactivity, as compared with mixtures of *Parietaria* allergen components having cross-reactivity because page 7, lines 5-31 of the reference discloses that a mixture of peptides may be used either as an immunogen in a composition or as a diagnostic agent is unpersuasive because the reference teaches purification of Par j1 by SDS page and further purification procedures (In particular, Example 1) and contacting purified Par j 1 with serum to diagnose allergy.

Applicant's argument that the reference does not teach the use of any of the proteins or peptides as reagents to distinguish between genuine *Parietaria* pollen sensitization and cross-reaction-mediated seropositivity to *Parietaria* pollen extract is unpersuasive. The reference teaches the use of Par j 1 to diagnose individuals having *Parietaria* allergy and does not need to teach these propositions to anticipate the claimed invention. Those of ordinary skill in the art need not know about cross-reaction mediated seropositivity to *Parietaria* pollen extract to teach a diagnostic for *Parietaria* pollen allergy using Par j 1. The knowledge of this phenomenon does not provide the basis for patentability. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or

functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Applicant's argument that pooled serum does not diagnose individuals is unpersuasive. It is well known by those of ordinary skill in the art that many diagnostic procedures pool serum for high-throughput analysis. Pooled serum which demonstrates a positive reaction is further analyzed to determine which specific individual is reactive and each of individuals in non-reactive pooled serum is negative for the diagnostic. Even if pooled serum couldn't be used to diagnose allergic individuals, the general teaching of entire reference is directed to Par j 1 and its use for diagnosis of Parietaria pollen allergic individuals. That teaching alone is sufficient to anticipate the claimed invention.

Applicant's arguments that: 1) *Parietaria* is a Mediterranean weed; 2.) *P. judaica* is not reported as occurring in Canada so Canadians can be anticipated to have a very low risk of being primarily sensitized to *P. judaica; 3.) Canadian patients in EP ' 065 have IgE that binds to extract of P. judaica* pollen; 4.) Patients from the U.S. (having very few occurrences of *P. judaica)* did not have any IgE against the pure allergen component Par j 2, despite showing binding to *P. judaica* extract; 5.) Sera from patients from Scandinavia, the U.S. and Austria contained IgE that binds to components in *Parietaria* extract (i.e. not pure components) but only a few Austrian and no Scandinavian or American patients' sera had IgE that bound to Par j 2 (i.e. to the pure component); and 6.) Mediterranean patients, who are primarily sensitized to

Parietaria, contained IgE that bound to Par j 2 are all unpersuasive. As argued *supra*, the authors of the reference need not know about and the reference need not teach the phenomenon of cross-reaction mediated seropositivity in order to anticipate the claimed invention. The reference teaches using the same compound to diagnose the same allergy. Therefore, the claims are anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 30, 33-34 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0707065 A2 in view of Duro et al. (IDS filed on 07/01/2002) for the same reasons as set forth in the Office Action mailed on 04/03/2008.

EP 0707065 teaches a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic (grass allergic) as *Parietaria* allergic, comprising selecting an individual known to be weed pollen allergic (grass allergic), wherein it is not known if the individual is *Parietaria* allergic; selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity; contacting serum from an the selected individual with the

pure allergen component, wherein the pure allergen component is pure Par j 1 allergen component; determining the presence of IgE binding to said pure Par j 1 component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component; wherein the pure allergen component is recombinant Par j 1. (In particular, page 4, lines 41-47, page 5, lines 31-32, page 7, lines 5-31, page 8, lines 49-59, Figure 8, abstract).

It is noted that the recitation of "an individual known to be weed pollen allergic" is anticipated both by grass pollen allergic individuals shown in Example 8 and by the fact that the diagnostic method of EP 0707065 is directed toward diagnostic procedures for all individuals. Grass pollen allergic individuals are a subset of all individuals which are encompassed by the teachings of the reference. A diagnostic procedure which identifies *Parietaria* allergic individuals from all individuals will inherently identify *Parietaria* allergic individuals from weed pollen allergic individuals.

The claimed invention differs from the prior art in the recitation of "wherein the pure allergen component is Par j 2" in claim 33; and "wherein the pure allergen component is recombinant Par j 2" in claim 36.

Duro et al., teaches contacting serum with recombinant Par j 2 to detect pollen allergy. The reference also teaches that Par j 2 is a new major allergen of *Parietaria judaica* pollen that reacts with the IgE of 82% of *Parietaria judaica* pollen sensitive patients.

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute Par j 2 for Par j 1 in the diagnostic method of EP 0707065 because Duro et al. teaches that Par j 2 is a major allergen of *Parietaria judaica* pollen that reacts with the IgE of 82% of *Parietaria judaica* pollen sensitive patients. One of ordinary skill in the art would have expected a high rate of success from using Par j 2 to diagnose *Parietaria judaica* allergy.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 08/04/2008 have been fully considered, but are not found persuasive.

Applicant argues:

"Moreover, the deficiencies of EP '065 are not resolved by Duro et al. In this regard, the teachings of Duro et al have been discussed in detail in various of Applicants' previous responses. Particularly, Duro et al fail to teach a method for serologically identifying an individual known to be weed pollen allergic wherein it is not known if the individual is *Parietaria* allergic. That is, the Duro et al publication is directed to a single allergen source, namely *Parietariajudaica* pollen, and does not mention other allergen sources or individuals known generally to be weed pollen allergic. While Duro et al seek to characterize one of at least 9 allergen components of this source, namely Par j 2, Duro et al are not concerned with any other allergy source. Further, by showing that 82% of the *Parietaria judaica* pollen sensitive patients' serum had IgE reacting with Parj 2, Duro et al merely show that Parj 2 is a major allergen (see page 297, right column, lines 18-21), and no other findings or conclusions are provided by Duro et al. Particularly, Duro et al do not teach or suggest that Par j 2, or any other pure allergen component, can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual, as recited in the present claims. In fact, while claim 30 recites the step of selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, Duro et al employs serum from individuals known to be *Parietaria* allergic. Further, while claim 30 requires selecting a pure *Parietaria* allergic component known to have limited or no cross- reactivity, Duro et al fail to teach, suggest or recognize that Parj 2 has limited or no cross- reactivity.

Importantly, Duro et al provide no teaching or suggestion that Par j 2 is a known pure allergen component with limited or no cross-reactivity. The previously submitted Declaration Under 37 C.F.R. 1.132 of the co-inventor Dr. Paolo Colombo confirms that the Duro et al paper does not disclose or suggest that the Par j 2 allergen has limited or no cross-reactivity with allergen components from other weed pollen allergen sources (paragraph 4) and thus does not teach or suggest using Par j 2, or any other purified allergen component, in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources (paragraph 4). As Duro et al do not teach or suggest that Par j 2 is a pure allergen component with limited or no cross-reactivity, and therefore suitable for use in identifying an individual known to be weed pollen allergic as *Parietaria* allergic, Duro et al do not disclose a method for such identification and do not resolve the defieincies of EP '065. Only in light of Applicants' specification can the Examiner conclude that Duro et al's patients having serum which do not react with Par j 2 are inherently not allergic to *Parietaria judaica* and Duro et al's patients having serum which reacts with Par j 2 are *Parietaria* allergic.

In determining patentability under 35 U.S.C. § 103, it is necessary to determine whether there was an apparent reason to combine the known elements in the fashion of the claim at issue, *KSR International Co. v. Teleflex, Inc.,* 127 S.Ct. 1727, 1740-41 (2007). Neither EP '065 not Duro et al provide any apparent reason to combine their teachings in a manner resulting in the methods of the present invention. Accordingly, the combination of EP '065 and Duro et al does not render the present methods obvious, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested."

Arguments with regard to EP 070765 have been discussed *supra*.

It remains the Examiner's position that 1.) Duro et al. teaches contacting serum with recombinant new major allergen Par j 2 of *Parietaria judaica* pollen to detect pollen allergy that reacts with the IgE of 82% of *Parietaria judaica* pollen sensitive patients and 2.) It would have been obvious to one of ordinary skill in the art at the time of invention to substitute Par j 2 for Par j 1 in the diagnostic method of EP 0707065 because Duro et al. teaches that Par j 2 is a major allergen of *Parietaria judaica* pollen that reacts with the IgE of 82% of *Parietaria judaica* pollen sensitive patients.

Applicant's argument that the reference does not teach the use of any of the proteins or peptides as reagents to distinguish between genuine *Parietaria* pollen sensitization and cross-reaction-mediated seropositivity to *Parietaria* pollen extract is unpersuasive. The references teach the use of Par j 1 and Par j 2 to diagnose individuals having *Parietaria* allergy and do not need to teach these propositions to anticipate the claimed invention. Those of ordinary skill in the art need not know about cross-reaction mediated seropositivity to *Parietaria* pollen extract to teach a diagnostic for *Parietaria* pollen allergy using Par j 1 or Par j 2. The knowledge of this phenomenon does not provide the basis for patentability. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Applicant's argument that Duro et al only shows that Parj 2 is a major allergen but does not teach or suggest that Par j 2 can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual is unpersuasive. Duro et al. is being relied on for its teaching that Par j 2 is a major allergen that can be used to distinguish individuals based upon their IgE binding profile. As evidenced by the specification and the instant response, the *Parietaria* allergic individuals whose serum didn't bind Par j 2 must inherently not be *Parietaria* allergic at all, providing evidence for the effectiveness of its use in diagnostic purposes. Knowledge of non-cross-reactivity of Par j s is not necessary. The combination of references teaches that Par j 1 and Par j2 can be used to diagnose *Parietaria* allergy by contacting serum from individuals with the purified allergens. Therefore, the rejection stands.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 19, 2008
Nora M. Rooney
Patent Examiner
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/Maher M. Haddad/
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Primary Examiner,
Art Unit 1644